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31200-69244



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| *Group:* | 1625 |
| *Confirmation No.:* | 8120 |
| *Application No.:* | 10/018,308 |
| *Invention:* | ISOFLAVONE METABOLITES |
| *Applicant:* | George Eustace Joannou |
| *Filed:* | January 24, 2002 |
| *Attorney Docket:* | 31200-69244 |
| *Examiner:* | Amelia A. Owens |

Certificate Under 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231

on August 2, 2004

(Signature)

Kim Tyree

(Printed Name)



RESPONSE

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

The following remarks are submitted in response to the March 23, 2004 official action.

The Examiner rejected claims 1 and 7-9 under 35 U. S. C. § 112, second paragraph. The Examiner conceded that the specification was enabling for the compound, but took the position that the specification is not enabling for pharmaceutically acceptable salts or prodrugs thereof. In support of her position, the Examiner cited In re Wands. As the Examiner has separately analyzed the specification against each point enumerated in In re Wands, Applicant has similarly considered each point and comments as set forth below.

1. The nature of the invention is fundamentally the novel compounds I and II of claim 1. Pharmaceutical compositions of those novel compounds and pharmaceutically acceptable salts and prodrugs thereof are included in claim 1.

2. The state of the prior art, namely, formulating compounds, pharmaceutically acceptable salts and prodrugs of isoflavenoids or any other organic compound, would be known by a person skilled in the art. The Examiner's attention is directed to Remington, The Science and Practice of Pharmacy, 20th edition, 2000, or Martindale: The Complete Drug Reference, previously titled Martindale: The Extra Pharmacopeia.

3. The predictability of preparing such pharmaceutically acceptable salts and prodrugs of the active compounds is discussed below in Items 7/8 - the quantity of experimentation required.

4. The amount of direction or guidance present is found on pages 21-22 and 26 of the specification. This is quite adequate disclosure to a person skilled in the art. There is no requirement for a description to exemplify every compound, pharmaceutically acceptable salt and prodrug that is claimed. The question is whether what is described provides sufficient information to amount to a real and reasonably clear disclosure. Applicant submits that it would be reasonable for a person skilled in the art to extrapolate from the disclosure to the compounds, pharmaceutically acceptable salts and prodrugs that are claimed.

A person skilled in the art would certainly possess knowledge sufficient to formulate appropriate pharmaceutically acceptable salts. The description and enablement requirements are to disclose the invention to a technical person. Only routine preparation of the salts is required by the person skilled in the art. It would be clear to reasonably competent persons having knowledge of the subject and having reasonable skill how to prepare appropriate pharmaceutically acceptable salts and prodrugs of the compounds.

5. There are no working examples of pharmaceutically acceptable salts or prodrugs. However, as indicated above, a person skilled in the art would readily know as part of his or her knowledge and training how to prepare such salts and prodrugs. It is not necessary for such salts or prodrugs to have been made or tested and it is routine for a skilled person to prepare such salts and prodrugs.

6. The breadth of the claims is as stated by the Examiner.

7/8. The quantity of experimentation need is as indicated above, at most routine trial and error to be performed by the skilled person. The level of skill in the art is in essence the knowledge of those ordinarily skilled in the art to whom the specification is addressed, who would be expected to have as part of their ordinary professional knowledge. To prepare pharmaceutically acceptable salts and prodrugs of a compound is routine to such

skilled persons and is described in numerous basic pharmaceutical texts.

As indicated above, it is not necessary for salts or prodrugs to have been made or tested as these are matters of routine preparation. A salt is conventionally regard as including two components, and anion and a cation. "Pharmaceutically acceptable salt" has a common meaning to a skilled person. It is well-established that the adequacy of the specification is evaluated through the eyes of a person skilled in the field. It is well-established that the skilled person may be expected to carry out normal routine trials. There is no dispute as to the knowledge of such a skilled person. The skilled person would have a basic pharmaceutical knowledge and skills of a formulator. As such, the skilled person would have the skills necessary to carry out routine trials and to make the salts and prodrugs. A skilled person is well aware that pharmaceutical compounds can exist as salts and prodrugs and conversion to such salts and prodrugs may improve the stability of the compounds. Many widely recognized pharmaceutical textbook establish that such pharmaceutically acceptable salts and prodrugs are within the skill of those skilled in the art of preparing pharmaceutical compounds.

In interpreting the scope of the claims, words are given their ordinary meanings and usage as understood by one of ordinary skill in the art. The person of ordinary skill in the art would understand how to formulate pharmaceutically acceptable salts and prodrugs of the novel compounds claimed in claim 1 by routine experimentation. The art to which the application relates is pharmaceutical chemistry. A person of ordinary skill in pharmaceutical chemistry would understand the synthesis of pharmaceutical compounds, and pharmaceutically acceptable salts and prodrugs of such compounds. A skilled person would refer to standard texts to support what the skilled person knows. Salts do not change the intrinsic properties of the active agent (Remington, The Science and Practice of Pharmacy, at 704) and standard salts are common compounds. The therapeutic agent is the invention. It is routine for the ordinarily skilled person in this art to formulate the therapeutic agent as a salt or prodrug.

Applicant submits that pharmaceutically acceptable salts and prodrugs of compounds I and II of claim 1 would have been clear to a person skilled in the art at the relevant date who could have performed routine experimentation to formulate the same.

Applicant hereby petitions for a two month extension of the term for response to the March 23, 2004 official action from June 23, 2004 to August 23, 2004. The Commissioner is authorized to charge the $210.00 fee for the extension of time, as well as any other fees which may be due in order to constitute this a timely response to the March 23,

2004 official action, to Deposit Account 10-0435 with reference to Applicant's undersigned counsel's file 31200-69244. A duplicate copy of this authorization is enclosed for that purpose.

Respectfully submitted,

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